K001780

JUL 3 1 2001

510(k) Summary
for
Copan Viral Transystem

1. SPONSOR

Copan Diagnostics Inc.
2175 Sampson Avenue, Unit 124
Corona, CA 91719

Contact Person: Norman Sharples
Telephone: 1-800-216-4016

Date Prepared: July 26, 2001

2. DEVICE NAME

Proprietary Name: Copan Viral Transystem
Common/Usual Name: Transport and Culture Medium Devices
Classification Name: Transport and Culture Medium Devices

3. PREDICATE DEVICES

Becton Dickinson Viral Culturette (K800832)
Medical Wire & Equipment Co. Virocult (K872213)

4. DEVICE DESCRIPTION

The Copan Viral Transystem products are offered in single plastic applicator, aluminum wire applicator, and flexible twisted wire applicator configurations. Each Copan Viral Transystem is composed of a sterile peel pouch containing a rayon- or Dacron-tipped swab used to collect the sample and a tube containing a polyurethane foam sponge soaked with liquid transport medium. The foam sponge functions as a simple holding reservoir for the transport medium. After sampling, the swab applicator is placed inside the tube and the tip of the swab makes contact with the sponge reservoir.

The Copan Viral Transystem medium consists of a balanced salt solution for maintaining osmotic pressure within physiological limits and phosphate buffers to stabilize the pH of the medium. Sodium thioglycollate reducing agent is also present.

To use the Copan Viral Transystem, the sterile peel pouch is opened and the cap is removed from the transport tube. The applicator swab is removed from the pouch and used to collect the clinical specimen. During specimen collection, the applicator tip should only touch the area where the infection is suspected.

5. INTENDED USE

The Copan Viral Transystem products are sterile, single-use specimen collection chambers intended to preserve the viability of viruses after their collection and during their transport from the collecting area to the laboratory. These devices are intended for the collection, transport, and preservation of clinical specimens for viral culture. The Copan Viral Transystem products are designed to support the viability of a variety of clinically important viruses.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The Copan Viral Transystem products are substantially equivalent in design, intended use, and overall function to other commercially distributed products used for the collection and transport of viruses. Specifically, the Copan Viral Transystem products are substantially equivalent to the Becton Dickinson Viral Culturette (K800832) and the Medical Wire & Equipment Co. Virocult products (K872213).

The Copan Viral Transystem and the substantially equivalent products are all sterile, single-use devices intended for use in the collection, transport, and preservation of viral specimens for culture. The proposed and predicate devices are equivalent in design and function in that single applicators are used for collection of the specimen and the swab applicator is then inserted into a tube containing medium for transport and preservation.

7. PERFORMANCE TESTING

Studies were conducted to evaluate the performance characteristics of the Copan Viral Transystem. Recovery studies were performed using Copan and comparative products to determine the ability of the products to maintain viability of viruses

during storage and use. Recovery studies were performed using a variety of viruses. Swabs were dosed with inoculum and inserted into the transport tube containing media. The tubes were stored at 4°C and room temperature (23°C) prior to subculturing onto appropriate media. All organisms tested remained viable for at least 24 hours.

Stability studies were performed on the Copan Viral Transystem products to support performance for a 15-month expiration date. All testing was performed at 1 month, 12 months, and 15 months after manufacture and gamma radiation sterilization of the finished product. Recovery testing, pH testing, and visual inspection testing were performed which demonstrated the stability of the Copan Viral Transystem device over its 15-month shelf life.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUL 3 1 2001

Copan Diagnostic Inc.
c/o Ms. Cynthia A. Sinclair, RAC
Medical Device Consultants, Inc.
49 Plain Street
North Attleboro, MA 02760

Re: 510(k) Number: K001780
Trade/Device Name: Copan Viral Transystem
Regulation Number: 866.2390
Regulatory Class: I
Product Code: JSM
Dated: May 18, 2001
Received: May 21, 2001

Dear Ms. Sinclair:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

JUL 3 1 2001

510(k) Number (if known): K001780

Device Name: Copan Viral Transystem

Indications For Use: The Copan Viral Transystem is indicated for the collection, transport and preservation of clinical specimens for viral culture and is intended to preserve the viability of viruses after their collection and during their transport from the collecting area to the laboratory.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Woody Dubois

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K001780

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)